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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

November 22, 2002

VIA FEDERAL EXPRESS

Marvin Elliot Ellis, President
Ellis Brothers Pecans, Inc.
1315 Tippettville Road
Vienna, GA 31092

Warning Letter
03-ATL-5

Dear Mr. Ellis:

On May 16-28, 2002, an investigator from the Food and Drug Administration (FDA), B. Douglas Brogden, conducted an inspection of your plant located at Vienna, Georgia. The inspection was conducted to determine your compliance with food labeling requirements of the Federal Food, Drug, and Cosmetic Act (the Act), and FDA's Emergency Permit Controls and Good Manufacturing Practices for Acidified Foods (21 Code of Federal Regulations (CFR), Parts 108 and 114). You can find the Act and food labeling requirements through links in FDA's home page at *http://www.fda.gov.*

During the inspection our investigator collected labels for various products manufactured by your firm under the "We're Nuts...(To Sell This Low)" brand. We (FDA) have limited our label review to the following four products, which we have determined to be sufficiently representative of the labeling deficiencies of your products: "[redacted]BBQ SAUCE," "[redacted]SWEET ONION BAR-B-QUE SAUCE," "PEANUT BRITTLE" and "STRAWBERRY FIG PRESERVES." These products are considered to be misbranded within the meaning of section 403(i)(2) of the Act in that their labels fail to declare the name of the components of various ingredients in accordance with 21 CFR 101.4(a)(1) and 101.4(b)(2). Specifically, the components of ketchup, mustard, worcestershire sauce, tomato sauce, margarine, and [redacted] must be declared by one of the two methods described in 21 CFR 101.4(b)(2). A copy of 21 CFR 101.4(b)(2) is enclosed. Also, the ingredient declared by the trade name "[redacted] must be declared by its common or usual name.

The product identified as "STRAWBERRY FIG PRESERVES" is misbranded under Section 403(i)(1) of the Act and 21 CFR 101.22 in that the label fails to bear a common or usual name that accurately describes the nature of the product. In addition, this product is misbranded because it fails to comply with 21 CFR 101.22. The phrase "natural flavor" or "artificial flavor" must be included in the statement of identity when an ingredient is used that simulates,

resembles or reinforces the characterizing flavor. Based on the formulation provided to the investigator, it appears that this product derives the characterizing strawberry flavor from strawberry [redacted]

We note that a number of your products are identified as preserves (e.g., "strawberry....) and appear to contain artificial colors, artificial flavors and gelatin as added ingredients. FDA has established a standard of identity for fruit preserves and jams in 21 CFR 150.160, which does not provide for the use of artificial colors, artificial flavors and gelatin. Products labeled as a "preserve" or "jam" must comply with the labeling and compositional requirements of the standard of identity, otherwise the food may be misbranded within the meaning of 403(g) of the Act.

The above labeling violations are not meant to be an all-inclusive list of all of the deficiencies on your food labels. It is your responsibility to ensure that all your products are labeled in accordance with the statutes enforced by FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from continuing to misbrand food.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these labeling violations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining labeling violations.

In addition to the serious labeling violations discussed above, our investigator also documented deviations from the Acidified Foods regulations, (21 CFR Part 114). The deviations documented by our investigator cause your acidified food products to be in violation of section 402(a)(4) of the Act. Acidified foods processed in violation of the mandatory requirements of 21 CFR 108.25 and 114 are adulterated, according to the Act, because they have been prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. The Emergency Permit Control regulation, (21 CFR Part 108), was issued pursuant to Section 404 of the Act. You can find the Act, the Emergency Permit Control and Acidified Foods regulations through links in FDA's home page at *http://www.fda.gov*. At the conclusion of the May inspection you were presented with a Form FDA-483 listing deviations from the Acidified Foods regulations (21 CFR Part 114). The deviations of concern are as follows:

1. Your firm failed to maintain processing and production records showing adherence to scheduled processes, including records of pH measurements, and other critical factors (e.g., fill temperature) intended to ensure a safe product, and containing sufficient additional information such as product code and container size to permit a public health hazard evaluation of the processes applied to each lot, batch or other portion of production [21 CFR 108.25(g) and 114.100(b)].

   Inspection of your firm's plant conducted May 16-28, 2002 reveals that your firm's production report records and pH test results records fail to include any reference to

product code or container sizes. Furthermore, your firm's production report records fail to record fill temperatures or record the minimum temperature, processing temperature and processing time specified as critical when you filed processing information for your firm's acidified food products. Review of scheduled process information for acidified foods manufactured by your firm and filed by your firm on FD Form 2541a raises questions about what temperatures are critical – the fill temperature, or the minimum initial temperature, process temperature and corresponding process time? We suggest you contact your process authority to review the critical factors in your process, review the instructions for filing acidified food scheduled process information (enclosed), and then replace, as appropriate, previously filed scheduled process information.

2. Your firm failed to mark each container or product with an identifying code permanently visible to the naked eye with identification specifying in code the establishment where the product was packed, the product contained therein, and the year, day and period packed [21 CFR 114.80(b)].

   Inspection of your firm's plant conducted May 16-28, 2002 reveals that your firm failed to code any of the acidified foods manufactured by your establishment during 2001.

This letter may not list all the deviations from 21 CFR 108.25 and 114 at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Acidified Food regulations (21 CFR Part 114), and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Barbara A. Wood

Barbara A. Wood, Acting Director
Atlanta District

Enclosures

cc: Keith M. Ellis, Vice President and Plant Manager
Ellis Brothers Pecans, Inc.
1315 Tippettville Road
Vienna, GA 31092-